

Appln. No.: 10/810,768
Amendment Dated June 22, 2009
Reply to Office Action of January 22, 2009

HQS-107US

Amendments to the Drawings:

The attached sheet of drawings includes changes to Figure 3. This sheet replaces the original sheet.

Attachment

Remarks/Arguments:

Claims 16-18, 20-38, and 42-45 are presently pending. All pending claims stand rejected. Applicants herein amend claims 16, 30-34, 36, 39, and 42. Support for the claim amendments can be found throughout the application as originally filed. For example, see the original application at page 6, lines 16-30, and Figure 3, and see U.S. Patent 7,314,046 (which was published as U.S. Patent App. Pub. No. 2003/0209246 and incorporated by reference in the original application at page 2, lines 2-3) at column 27, lines 15-28. No new matter has been added. Reconsideration is respectfully requested in view of the above amendments and the following remarks.

Drawings Objections

On page 2, the Office Action recites that "the drawings are object to...because they do not include the following reference sign(s) mentioned in the description: 422." Applicants have amended Figure 3 herein to include the reference sign "422." Therefore, Applicants respectfully request that this objection be withdrawn.

On page 2, the Office Action recites that "the drawings are objected to [for failing to] show every feature of the invention specified in the claims." Specifically, the Office Action recites that "the delivery tube, fitting and nasal cannula must be shown or the feature(s) canceled from the claim(s)." Applicants contend that they are entitled to incorporate this information by reference under 37 C.F.R. § 1.57. Applicants respectfully note that Figures including the above-specified features may be found in U.S. Patent 7,314,046 (the '046 patent), which was published as U.S. Patent App. Pub. No. 2003/0209246 and was incorporated by reference in the original application at page 2, lines 2-3. Specifically, Figure 1 of the '046 patent shows delivery tube 28, fitting 26, and nasal cannula 29. Accordingly, Applicants respectfully submit that all features of the claims are shown in the Figures. Therefore, Applicants respectfully request that this objection be withdrawn.

Claim Rejections Under 35 U.S.C. § 112

On page 3, the Office Action recites that "[c]laims 16-18, 20-39, 42-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement." Applicants contend that they are entitled to incorporate such information by

reference under 37 C.F.R. § 1.57 and respectfully note that a written description supporting the above-specified features may be found in the '046 patent, which was incorporated by reference in the present specification in the preliminary amendment filed on July 12, 2004.

Pages 3-5 of the Office Action enumerate a number of allegedly unsupported features of the claims that are supported by the '046 patent. The allegedly unsupported claim language is listed below, with reference to exemplary locations in the '046 patent where support for this language may be found:

- supply unit to deliver "heated and humidified gas" or heats a breathing gas and combines the breathing gas with water vapor. Col. 6, lines 33-39.
- a delivery tube. Col. 5, lines 10-11 (delivery tube 28).
- a fitting. Col. 7, lines 22-24 (connector block 26).
- a delivery tube assembly configured to transfer heat to the heated and humidified gas received from the supply unit. Col. 6, lines 45-49.
- a nasal cannula. Col. 7, lines 29-32 (cannula 29).
- in claim 18, a supply unit configured to deliver humidified gas at a flow rate above about 20 liters per minute. Col. 12, lines 54-58.
- in claims 30, 31, 33, a method for delivering heated and humidified gas to a neonatal patient. Col. 32, line 61 - Col. 34, line 23.
- in claim 32, delivering "only" heated and humidified gas through the cannula. Cannula 29 is connected to delivery tube 28, which is connected to the supply unit. Only heated and humidified air is delivered from the supply unit.
- in claim 34, fluid flowing through and reversing direction in the delivery tube. Col. 5, lines 25-33 (heating fluid (supply) lumen 74 and return lumen 76).

Accordingly, Applicants submit that all of the features of the claims are supported by the written description. Therefore, Applicants respectfully request that this rejection be withdrawn.

On page 5, the Office Action recites that "[c]laims 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite." Applicants have amended claim 42 to clarify that the heated and humidified gas is heated with the humidification fluid. Therefore, Applicants respectfully request that this rejection be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

On page 5, the Office Action recites that "[c]laims 16-18, 20-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniell et al. (US 6,050,260) in view of Ko et al. '527." Applicants respectfully traverse this rejection. While not conceding the rejection, Applicants herein amend independent claims 16, 32, 34, and 39 in order to advance prosecution.

Claims 16-29

Independent claim 16 is directed to a system for delivering humidified gas to a patient including

a supply unit including:

a water heater for heating a humidification fluid; and

a humidifier having a breathing gas flow passage and a humidification fluid flow passage, the humidifier configured to heat and humidify a breathing gas in the breathing gas flow passage with the heated humidification fluid;

a delivery tube assembly...configured to pass the heated humidification fluid from the water heater for delivery to the humidification fluid flow passage, to pass the heated and humidified gas received from the breathing gas flow passage, and to transfer heat from the heated humidification fluid to the heated and humidified gas received from said supply unit....

This means the system has a supply unit including a water heater for heating a humidification fluid and a humidifier. The humidifier has a breath gas flow passage and a humidification fluid flow passage. The humidifier is configured to heat and humidify breathing gas in the breathing gas flow passage with the heated humidification fluid. The system further has a delivery tube assembly. The delivery tube assembly is configured to pass the heated humidification fluid from the water heater for delivery to the humidification fluid flow passage. The delivery tube assembly is also configured to pass the heated and humidified gas received

from the breathing gas flow passage. The delivery tube assembly is further configured to transfer heat from the heated humidification fluid to the heated and humidified gas received from the supply unit.

Applicants respectfully submit that Daniell in view of Ko fails to disclose, teach, or suggest all of the features of independent claim 16. Daniell is directed to a humidifier for treating sleep apnea. Daniell discloses a gas delivery system having a nasal mask 2 and an inspiratory conduit 3. Inspiratory conduit 3 is connected to a humidification chamber 5 having inlet 16, outlet 4, and containing a volume of water 6. In operation, a blower 15 blows air through inlet 16 into humidification chamber 5. A humidifier 8 including heating plate 7 heats the water 6 until water vapor combines with the blown air and humidified gas passes out of outlet 4 of humidification chamber 5 into inspiratory conduit 3. Daniell discloses that inspiratory conduit 3 may contain heating means or wires to heat the humidified gas in conduit 3. See Daniell at column 3, lines 40-61, column 4, lines 2-11, and Figure 1.

Daniel, however, fails to disclose, teach, or suggest that humidifier 8 includes both a breathing gas flow passage and a humidification fluid flow passage. Daniell solely discloses humidifier 8 having a passage for breathable air through inlet 16 and outlet 4. Daniell also fails to disclose, teach, or suggest that the system includes a water heater separate from the humidifier 8. Further, Daniell fails to disclose inspiratory conduit 3 configured to transfer humidification fluid from a water heater to a humidification fluid flow passage of the humidifier. Daniell solely discloses water 6 remaining in the humidification chamber 5. Finally, Daniell fails to disclose inspiratory conduit 3 configured to transfer heat from humidification fluid to the humidified gases in inspiratory conduit 3. Accordingly, for the above reasons, Applicants respectfully submit that Daniell fails to disclose, teach, or suggest at least the features of "a supply unit including...a water heater for heating a humidification fluid; and a humidifier having a breathing gas flow passage and a humidification fluid flow passage...; [and] a delivery tube assembly...configured to pass the heated humidification fluid from the water heater for delivery to the humidification fluid flow passage, ...and to transfer heat from the heated humidification fluid to the heated and humidified gas received from said supply unit," as recited in independent claim 16.

Applicants further submit that Ko fails to make up for the deficiencies of Daniell with respect to claim 16. Ko is directed to an apparatus for delivering continuous positive airway pressure to a patient. Ko fails to disclose a supply unit having a water heater and a humidifier.

Ko further fails to disclose a humidification fluid for use in humidifying and heating a breathable gas. Accordingly, Applicants respectfully submit that Daniell in view of Ko fails to disclose, teach, or suggest at least the features of "a supply unit including...a water heater for heating a humidification fluid; and a humidifier having a breathing gas flow passage and a humidification fluid flow passage...; [and] a delivery tube assembly...configured to pass the heated humidification fluid from the water heater for delivery to the humidification fluid flow passage, ...and to transfer heat from the heated humidification fluid to the heated and humidified gas received from said supply unit," as recited in independent claim 16. Therefore, Applicants respectfully request that the rejection of claim 16 be withdrawn.

Claims 17-29 each depend, either directly or indirectly, from independent claim 16. Accordingly, claims 17-29 include the allowable features discussed above with respect to independent claim 16. Therefore, Applicants respectfully request that the rejection of claims 17-29 be withdrawn for at least these reasons.

Claim 32

Independent claim 32, while not identical to claim 16, includes features similar to the allowable features discussed above with respect to claim 16. Specifically, claim 32 is directed to a method for delivering heated and humidified gas to a patient including:

heating a humidification fluid in the supply unit;

heating and humidifying a breathing gas in the supply unit separately from the heating of the humidification fluid, thereby producing a heated and humidified gas in the supply unit; and

delivering the heated and humidified gas and the heated humidification fluid from the supply unit, through the delivery tube such that the heated humidification fluid heats the heated and humidified gas in the delivery tube, and to the nasal cannula for delivery to the patient.

This means that a humidification fluid is heated in a supply unit. A breathing gas is heated and humidified in the supply unit separately from the heating of the humidification fluid, thereby producing a heated and humidified gas in the supply unit. The heated and humidified gas and the heated humidification fluid are then delivered from the supply unit and through a delivery tube and to a nasal cannula for delivery to a patient. In the delivery tube, the heated humidification fluid heats the heated and humidified gas.

Applicants respectfully submit that Daniell in view of Ko fails to disclose, teach, or suggest all of the features of independent claim 32. As discussed above, Daniell discloses an inspiratory conduit 3 connected to the humidification chamber 5 of a humidifier 8 containing a volume of water 6. Daniell fails to disclose, teach, or suggest delivering the water 6 from the humidifier 8. Daniell must therefore fail to disclose, teach, or suggest using water 6 to heat the humidified gas in the inspiratory conduit 3. Accordingly, Daniell fails to disclose, teach, or suggest "delivering the heated and humidified gas and the heated humidification fluid from the supply unit, through the delivery tube such that the heated humidification fluid heats the heated and humidified gas in the delivery tube," as recited in independent claim 32.

Applicants further submit that Ko fails to make up for the deficiencies of Daniell with respect to claim 32. As discussed above, Ko fails to disclose a humidification fluid for use in humidifying and heating a breathable gas. Accordingly, Applicants respectfully submit that Daniell in view of Ko fails to disclose, teach, or suggest at least the features of "delivering the heated and humidified gas and the heated humidification fluid from the supply unit, through the delivery tube such that the heated humidification fluid heats the heated and humidified gas in the delivery tube," as recited in independent claim 32. Therefore, Applicants respectfully request that the rejection of claim 32 be withdrawn.

Claims 30, 31, and 33

Independent claim 30 is directed to a method for delivering heated and humidified gas to a neonatal patient. Independent claim 31 is directed to a method for assisting respiration in a neonatal patient. Independent claim 33 is directed to a method for delivering heated and humidified gas to a nasal passageway of a neonatal patient. Each of claims 30, 31, and 33, as amended, includes the step of delivering the heated and humidified gas from a supply unit to a neonatal patient through a delivery tube and a nasal cannula at a flow rate of about 1 liter per minute to about 8 liters per minute and at water vapor content of at least about 40 milligrams per liter.

On page 6, the Office Action recites that "[r]egarding claims 30, 31, 33, using the device for a neonatal patient would have been obvious in order to comprehend different sized patients. The exact flow rates and humidity levels used during operation of the device is well within the realm of the practitioner of ordinary skill in order to compensate for practical considerations of

intended use dependent on the requirements for each individual patient." Applicants respectfully disagree for the reasons set forth below.

Preliminarily, "[o]fficial notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." See MPEP 2144.03(A). Applicants submit that the Office Action provides no documentary evidence to support the broad assertion that the flow rates and humidity levels recited in claims 30, 31, and 33 would have been within the realm of the practitioner of ordinary skill. Applicants further respectfully submit that this conclusion is unsupported by the references cited in the Office Action. Applicants respectfully contend that "the exact flow rates and humidity levels (or water vapor content)" claimed are not well-known or a matter of common knowledge in the art, as will be explained below. Therefore, Applicants respectfully request that documentary evidence be provided to support this assertion by the Office Action or that the rejection of claims 30, 31, and 33 be withdrawn.

An applicant for patent may submit objective evidence of non-obviousness in the form of a declaration including evidence of long-felt but unsolved need of others and commercial success to rebut a rejection for obviousness. See MPEP § 716.01(a). Establishing that the claimed invention satisfies a long-felt need requires objective evidence that "[f]irst, the need must have been a persistent one that was recognized by those of ordinary skill in the art...[s]econd, the long-felt need must not have been satisfied by another before the invention...[and] [t]hird, the invention must in fact satisfy the long-felt need." See MPEP § 716.04(I). Further, an applicant asserting commercial success must establish a nexus between the claimed invention and evidence of commercial success. See MPEP § 716.03(I).

Applicants submit the declaration of inventor Owen Bamford in support of the following statements.

It is submitted that prior to Applicants' claimed invention, it was not known how to deliver heated and humidified flows of gas (up to 8 liters per minute) at a high water vapor content (at least about 40 milligrams/liter) through an infant nasal cannula. It is further submitted that prior to Applicants' invention, only low flows of gas could be delivered through an infant nasal cannula without condensation of the water vapor in the gas. Moreover, prior

respiratory therapies for neonatal patients risked potentially damaging the airway of the patient through mechanical insertions or erosion of soft tissue.

To the contrary, the method of Applicants' invention avoids the risks associated with prior treatment options by providing heated and humidified flows of gas (up to 8 liters per minute) at a high water vapor content (at least about 40 milligrams/liter) through an infant nasal cannula. Applicants' claimed invention achieves this feature without the mechanical insertions or tight-fitting devices of prior therapies. This feature of Applicants' invention has provided physicians with a new and inexpensive, non-invasive, and non-traumatic option for neonatal respiratory therapy that satisfies a long-felt need in the field of respiratory support for neonatal patients.

Additionally, Applicants' VapoTherm 2000i device performs the function discussed above with respect to claims 30, 31, and 33. It is submitted that the VapoTherm 2000i device has achieved commercial success in replacing prior respiratory support treatments for neonatal patients. It is further submitted that this commercial success is due at least in part to the superiority of Applicants' method (as set forth in claims 30, 31, and 33) over prior respiratory therapies for neonatal patients, which has been well-documented in the publications described in the attached declaration.

Thus, Applicants respectfully submit that achieving the claimed flow rates and humidity levels for treatment of a neonatal patient would not have been obvious or within the realm of the practitioner of ordinary skill in the art, as indicated by the Office Action. Accordingly, Applicants respectfully submit that *Daniell in view of Ko* are inadequate to support a rejection for obviousness of claims 30, 31, and 33. Therefore, Applicants respectfully request that the rejection of claims 30, 31, and 33 be withdrawn.

Claims 34-38

Independent claim 34 is directed to a system for delivering heated and humidified gas to a patient including:

a supply unit that heats a breathing gas and combines the breathing gas with water vapor to form a heated and humidified gas in the supply unit; and

a delivery tube releasably coupled to the supply unit, the delivery tube being configured to transfer heat to the heated and humidified breathing gas received from the supply unit,

wherein the breathing gas is humidified in the supply unit by fluid that has flowed through the delivery tube.

This means that a supply unit combines breathing gas with water vapor to form a heated and humidified gas. A delivery tube is coupled to the supply unit and configured to transfer heat to the heated and humidified breathing gas received from the supply unit. The supply unit humidifies the breathing gas using fluid that has flowed through the delivery tube.

Applicants respectfully submit that Daniell in view of Ko fails to disclose, teach, or suggest all of the features of independent claim 34. As discussed above, Daniell discloses an inspiratory conduit 3 connected to a humidification chamber 5 having inlet 16, outlet 4, and containing a volume of water 6. A heating plate 7 heats the water 6 until water vapor combines with air in the humidification chamber 5. However, Daniell fails to disclose, teach, or suggest water 6 flowing through inspiratory tube 3. Accordingly, Daniell fails to disclose, teach, or suggest that "the breathing gas is humidified in the supply unit by fluid that has flowed through the delivery tube," as recited in independent claim 34.

Applicants further submit that Ko fails to make up for the deficiencies of Daniell with respect to claim 34. As discussed above, Ko fails to disclose a humidification fluid for use in humidifying and heating a breathable gas. Accordingly, Applicants respectfully submit that Daniell in view of Ko fails to disclose, teach, or suggest at least the features of "the breathing gas is humidified in the supply unit by fluid that has flowed through the delivery tube," as recited in independent claim 32. Therefore, Applicants respectfully request that the rejection of claim 34 be withdrawn.

Claims 35-38 each depend, either directly or indirectly, from independent claim 34. Accordingly, claims 35-38 include the allowable features discussed above with respect to independent claim 34. Therefore, Applicants respectfully request that the rejection of claims 35-38 be withdrawn.

Claim 39

Independent claim 39 is directed to a warming and humidifying system for a breathing gas including:

a fluid supply;

a means for heating the breathing gas with fluid from the fluid supply; and

a means for humidifying the breathing gas with the fluid after the fluid has heated the breathing gas.

This means that the system includes a means for heating a breathing gas with fluid from a fluid supply. The system further includes means for humidifying the breathing gas with the fluid after the fluid has heating the breathing gas.

Applicants respectfully submit that Daniell in view of Ko fails to disclose, teach, or suggest all of the features of independent claim 39. As discussed above, Daniell discloses an inspiratory conduit 3 connected to a humidification chamber 5 having inlet 16, outlet 4, and containing a volume of water 6. A heating plate 7 heats the water 6 until water vapor combines with air in the humidification chamber 5. However, Daniell fails to disclose, teach, or suggest that water 6 humidifies the breathable air after water 6 heats the air. Daniell solely discloses that water 6 contacts the air once as it passes through humidification chamber 5. Accordingly, Daniell fails to disclose, teach, or suggest "a means for humidifying the breathing gas with the fluid after the fluid has heated the breathing gas," as recited in independent claim 34.

Applicants further submit that Ko fails to make up for the deficiencies of Daniell with respect to claim 39. As discussed above, Ko fails to disclose a humidification fluid for use in humidifying and heating a breathable gas. Accordingly, Applicants respectfully submit that Daniell in view of Ko fails to disclose, teach, or suggest at least the features of "a means for humidifying the breathing gas with the fluid after the fluid has heated the breathing gas," as recited in independent claim 39. Therefore, Applicants respectfully request that the rejection of claim 39 be withdrawn.

Claims 42-45

On page 6, the Office Action recites that "[c]laims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 16-18, 20-39 above, and further in view of Verkaart." Applicants respectfully traverse this rejection. While not conceding the rejection, Applicants herein amend claim 42 in order to advance prosecution. Further, Applicants respectfully note that the Office Action fails to specify which Verkaart reference is being applied. Applicants will proceed under the assumption that the Examiner applies U.S.

applies U.S. Patent No. 5,097,898 to Verkaart, which is a division of U.S. Patent No. 5,063,994 to Verkaart.

Independent claim 42 is directed to a method of delivering a breathing gas to a patient including:

heating a humidification fluid in a heater in the supply unit;

heating and humidifying the breathing gas in a humidifier in the supply unit; [and]

heating the heated and humidified breathing gas with the humidification fluid in the delivery tube such that the humidification fluid flows from the heater, through the delivery tube, through the humidifier, and to the heater such that the fluid heats the heated and humidified breathing gas in the delivery tube and in the humidifier....

This means a humidification fluid is heated in a heater. A breathing gas is heated and humidified in a humidifier. The heated and humidified breathing gas is then heated in the delivery tube with the humidification fluid. The humidification fluid flows from the heater, through the delivery tube, through the humidifier, and back to the heater so that the humidification fluid heats the gas both in the delivery tube and in the humidifier.

Applicants respectfully submit that Daniell in view of Ko and further in view of Verkaart fails to disclose, teach, or suggest all of the features of independent claim 42. As discussed above, Daniell in view of Ko fail to disclose, teach or suggest flowing a humidification fluid outside of the humidifier and along a delivery tube in order to heat a breathable gas. Applicants respectfully submit that Verkaart fails to make up for the deficiencies of Daniell and Verkaart. Verkaart is directed to a heat exchanger. Verkaart discloses a heat exchanger having an inner flexible plastic tube 2 and an outer flexible plastic tube 4. The inner flexible plastic tube 2 carries infusates to a patient, while the outer flexible tube 4 carries a warming fluid. The system further includes a first end cap 6 for introducing the warming fluid into outer tube 4, and a second end cap 8 for withdrawing the warming fluid from outer tube 4. Verkaart discloses that the infusate in inner tube 2 is warmed by the warming fluid in the outer tube 4. See Verkaart at column 2, lines 39-50.

Verkaart, however, fails to disclose any further use for the warming fluid that is withdrawn from outer tube. Specifically, Verkaart fails to disclose that the withdrawn warming

fluid may be flown through a humidifier, or may be used to humidify a breathing gas. Additionally, Verkaart fails to disclose that the disclosed heat exchanger is suitable for heating a breathing gas in inner tube 2. Verkaart solely discloses a heat exchange for heating liquid infusates, which are injected into a patient. Accordingly, Applicants respectfully submit that Daniell in view of Ko and further in view of Verkaart fails to disclose, teach, or suggest "heating the heated and humidified breathing gas with the humidification fluid in the delivery tube such that the humidification fluid flows from the heater, through the delivery tube, through the humidifier, and to the heater such that the fluid heats the heated and humidified breathing gas in the delivery tube and in the humidifier," as recited in independent claim 42. Therefore, Applicants respectfully request that the rejection of claim 42 be withdrawn.

Claims 43-45 each depend, either directly or indirectly, from independent claim 42. Accordingly, claims 43-45 include the allowable features discussed above with respect to independent claim 42. Therefore, Applicants respectfully request that the rejection of claims 43-45 be withdrawn.

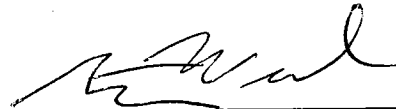
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Conclusion

In light of the above amendments and remarks, Applicants respectfully submit that the above application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,



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SJW/AJK/

Dated: June 22, 2009

Enclosures: Replacement Figure 3
Declaration of Inventor Owen Bamford

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The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

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